SAFETY DATA SHEET

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Lidocaine hydrochloride and epinephrine injection, solution (Hospira, Inc.)

Product Code(s) PZ03472
Synonyms Lignoocaine with epinephrine
Trade Name: Not applicable
Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product anesthetic agent

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements

Signal word Not classified
Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards
Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances
Substances Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Lidocaine Hydrochloride (CAS #: 73-78-9)	<=2		200-803-8	Acute Tox.4 (H302)	Not classified	No data available	No data available
Sodium metabisulfite USP (CAS #: 7681-57-4)	<0.1		231-673-0 (016-063-00-2)	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	Not classified	No data available	No data available
Epinephrine hydrochloride (CAS #: 329-63-5)	< 1		206-346-0	Not classified	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	< 0.1	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B ::	No data available	No data available

				Acute Tox. 3 (H331)	C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%		

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Lidocaine Hydrochloride 73-78-9	317	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Sodium metabisulfite USP 7681-57-4	1310	2000	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information
+ Substance with a Union workplace exposure limit
* Proprietary
** to adjust pH
Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire.

Explosion data

Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean

spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Lidocaine Hydrochloride

Pfizer OEL TWA-8 Hr: 300; STEL 2500 µg/m³, Skin

SODIUM CHLORIDE

Latvia	TWA: 5 mg/m³;
Russia	MAC: 5 mg/m³

Sodium metabisulfite USP

ACGIH TLV	TWA: 5 mg/m³
Denmark	TWA: 5 mg/m³; STEL: 10 mg/m³;
France	5 mg/m³
Ireland	TWA: 5 mg/m³; STEL: 15 mg/m³ (calculated;thoracic fraction);
Spain	TWA-(VLA-ED): 5 mg/m³;
Switzerland	TWA-MAK: 5 mg/m³; inhalable dust
OSHA PEL	(vacated) TWA: 5 mg/m³
United Kingdom	TWA: 5 mg/m³; STEL: 15 mg/m³;

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m³
ACGIH TLV	Ceiling: 2 mg/m³
Austria	TWA-TMW: 2 mg/m³; inhalable fraction STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction

Bulgaria	TWA: 2.0 mg/m³; alkaline aerosols
Czech Republic	1 mg/m³
	Ceiling: 2 mg/m³
Denmark	Ceiling: 2 mg/m³;
Estonia	TWA: 1 mg/m³;
	STEL: 2 mg/m³;
Finland	Ceiling: 2 mg/m³;
France	2 mg/m³
Hungary	TWA-AK: 1 mg/m³;
	STEL-CK: 2 mg/m³;
Ireland	STEL: 2 mg/m³;
Ceiling Limit Value	2 mg/m³
Latvia	TWA: 0.5 mg/m³;
Poland	TWA-NDS: 0.5 mg/m³;
	STEL-NDSCh: 1 mg/m³;
Romania	TWA: 1 mg/m³;
	STEL: 3 mg/m³;
Slovakia	TWA: 2 mg/m³;
Spain	STEL (VLA-EC): 2 mg/m³;
Switzerland	TWA-MAK: 2 mg/m³; inhalable dust
	STEL-KZGW: 2 mg/m³; inhalable dust
OSHA PEL	TWA: 2 mg/m³
	(vacated) Ceiling: 2 mg/m³
United Kingdom	STEL: 2 mg/m³;

+ Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	TWA-TMW: 5 ppm;
	TWA-TMW: 8 mg/m³;
	STEL-KZGW: 10 ppm (8 X 5 min);
	STEL-KZGW: 15 mg/m³ (8 X 5 min);
Bulgaria	TWA: 5 ppm;
	TWA: 8.0 mg/m³;
	STEL: 10 ppm;
	STEL: 15.0 mg/m³;
Czech Republic	8 mg/m³
	Ceiling: 15 mg/m³
Denmark	STEL: 5 ppm;
	STEL: 8 mg/m³;
Estonia	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
European Union	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Finland	STEL: 5 ppm;
	STEL: 7.6 mg/m³;
Germany DFG	TWA-MAK: 2 ppm; I(2);
	TWA-MAK: 3.0 mg/m³; I(2);
	Peak: 4 ppm;
	Peak: 6 mg/m³;
Germany TRGS	TWA-AGW; 2 ppm (exposure factor 2);
	TWA-AGW; 3 mg/m³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m³;
	TWA-AK: 5 ppm;

	STEL-CK: 165 mg/m³;
	STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m³;
	TWA: 5 ppm;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Italy MDLPS	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Ceiling Limit Value	2 ppm
	3.0 mg/m³
Latvia	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Netherlands	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Poland	TWA-NDS: 5 mg/m³;
	STEL-NDSCh: 10 mg/m³;
Romania	TWA: 5 ppm;
	TWA: 8 mg/m³;
	STEL: 10 ppm;
	STEL: 15 mg/m³;
Russia	MAC: 5 mg/m³
Slovakia	TWA: 5 ppm;
	TWA: 8.0 mg/m³;
	Ceiling: 15 mg/m³;
Spain	TWA-(VLA-ED): 5 ppm;
	TWA-(VLA-ED): 7.6 mg/m³;
	STEL (VLA-EC): 10 ppm;
	STEL (VLA-EC): 15 mg/m³;
Switzerland	TWA-MAK: 2 ppm;
	TWA-MAK: 3 mg/m³;
	STEL-KZGW: 4 ppm;
	STEL-KZGW: 6 mg/m³;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm
	7 mg/m³
OSHA PEL	Ceiling: 5 ppm
	Ceiling: 7 mg/m³
	(vacated) Ceiling: 5 ppm
	(vacated) Ceiling: 7 mg/m³
United Kingdom	TWA: 1 ppm; gas and aerosol mist
	TWA: 2 mg/m³; gas and aerosol mist
	STEL: 5 ppm; gas and aerosol mist
	STEL: 8 mg/m³; gas and aerosol mist

Pfizer Occupational Exposure Band (OEB) Statement: The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m^3 to 3000ug/m^3)
Epinephrine hydrochloride	
Pfizer Occupational Exposure Band (OEB):	OEB 4 (control exposure to the range of 1ug/m^3 to <10ug/m^3)

8.2. Exposure controls

Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Clear, colorless
Odor	No information available.
Odor threshold	No information available

Property	**Values**
Melting point / freezing point	No data available

Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity
Reactivity No information available.

10.2. Chemical stability
Stability Stable under normal conditions.

Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions No information available.

10.4. Conditions to avoid
Conditions to avoid Fine particles (such as mists) may fuel fires/explosions.

10.5. Incompatible materials
Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products
Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients

Short term Harmful if swallowed, May cause mild eye irritation. May cause slight skin irritation. (based on components) Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Known Clinical Effects: Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Lidocaine Hydrochloride

Rat Oral LD50 317 mg/kg
Rat Para-periosteal LD50 25 mg/kg
Rat Intraperitoneal LD50 133 mg/kg
Mouse Oral LD50 292 mg/kg
Mouse Intravenous LD50 19.5 mg/kg

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m^3
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Epinephrine

Rat Dermal LD50 62 mg/kg
Rat Oral LD50 30 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Sodium metabisulfite USP	= 1310 mg/kg (Rat)	> 2000 mg/kg (Rat)	-
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Irritation / Sensitization: (Study Type, Species, Severity)
Lidocaine Hydrochloride
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild
SODIUM CHLORIDE
Skin irritation Rabbit Mild
Eye irritation Rabbit Mild
Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe
+ Hydrochloric Acid
Skin irritation Severe
Eye irritation Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Lidocaine Hydrochloride
Embryo / Fetal Development Rat Subcutaneous 30 mg/kg NOAEL Not teratogenic
Embryo / Fetal Development Rat Intraperitoneal 56 mg/kg NOAEL Not Teratogenic
Embryo / Fetal Development Rat Intraperitoneal 72 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rat Intravenous 500 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Intraperitoneal 6 mg/kg LOAEL Developmental toxicity
Epinephrine
Embryo / Fetal Development Rat Intravenous Dose not specified Not teratogenic
Embryo / Fetal Development Rabbit Subcutaneous 30 times human dose LOAEL Developmental toxicity
Embryo / Fetal Development Mouse Subcutaneous 7 times human dose LOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Lidocaine Hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Mouse Negative
Epinephrine
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Sister Chromatid Exchange Negative with activation
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Equivocal without activation
+ Hydrochloric Acid
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Sodium metabisulfite USP
IARC Group 3
+ Hydrochloric Acid
IARC Group 3

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
Sodium metabisulfite USP	Not PBT/vPvB PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure

and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Lidocaine Hydrochloride

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-803-8

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present

Sodium metabisulfite USP

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-673-0
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5

Epinephrine hydrochloride

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	206-346-0

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78
Sodium metabisulfite USP 7681-57-4	RG 66

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018	Not applicable
Storage of Hazardous Material	Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20	Not applicable
Major Accidents Ordinance SR 814.012	Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium metabisulfite USP 7681-57-4	75	-
Sodium hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants
Not applicable

Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

Ozone-depleting substances (ODS) Regulation (EU) 2024/590
Not applicable.

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
Sodium metabisulfite USP 7681-57-4	Product-type 9: Fiber, leather, rubber and polymerized materials preservatives
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)
Not applicable

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment
Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15
H302 - Harmful if swallowed. H300 - Fatal if swallowed. H310 - Fatal in contact with skin. H318 - Causes serious eye damage. H314 - Causes severe skin burns and eye damage. H331 - Toxic if inhaled.

Data Sources:	Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Reason for revision	Updated Section 2 - Hazard Identification.
Revision date	13-Jun-2025
Prepared By	Pfizer Global Environment, Health, and Safety

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